Consommation et Affaires commerciales Canada
Bureau des brevets
Ottawa, Canada
K1A 0C9

Consumer and Corporate Affairs Canada
Patent Office

(21) (A1) 2,097,857
(22) 1993/06/04
(43) 1994/12/05

5,082,8/74

(51) INTL.CL. 5 A61N-001/36

# (19) (CA) APPLICATION FOR CANADIAN PATENT (12)

(54) Fes Method Improvements

(72) Haugland, Morten - Denmark ;
Hoffer, Andy - Canada ;
Sinkjaer, Thomas - Denmark ;

(71) Same as inventor

(57) 17 Claims

Notice: This application is as filed and may therefore contain an incomplete specification.

Canada

CCA 3254 (10-92) 41 7530-21-936-3254

# FES METHOD IMPROVEMENTS

The present invention relates to FES method improvements. In one aspect, the present invention relates to a novel principle for recording and using natural sensory nerve activity from peripheral nerves in a system for functional electrical stimulation (FES) wherein the artifact signal generated by muscle stimulation is minimized. In another aspect, the invention relates to the utilization of a specific slip-related signal for providing a secure grip of an object through FES os a partically or completely paralyzed muscle which is involved in holding the object.

## GENERAL BACKGROUND

It is possible to stimulate paralysed muscles electrically and in this way make paralysed limbs perform functional movements. This technique, called functional electrical stimulation (FES), has been known for decades and several research groups worldwide are currently involved in developing the technique. The research is directed more and more towards the development of implantable systems that use closed-loop control, since most previous systems have suffered from practical and cosmetical problems because of the external equipment and the difficult control of stimulated muscles. To develop such systems, it is necessary to develop sensors that are suitable for long-term implantation. Some necessary features of such sensors are biocompatibility, reliability, durability and small size. Very few artificial sensors have these features.

For a hand-grasp prosthesis or foot-drop prosthesis, nerve cuff electrodes might be implanted on individual nerves in the hand or foot. The signal is expected to tell when an object has contact with the skin (for example in the fingers, the nerve signal response when the object slips, and in the foot at impact between the sole and the ground surface). The signal can thus in a hand-grasp prosthesis be used for i.e.

updating the stimulation intensity if a grasped object starts to slip and also to detect the minimum stimulation intensity necessary for holding an object, and in the foot the nerve signal can be used to activate the ankle dorsiflexor muscles at the appropriate time during a step-cycle.

Human skin, joints and muscles are equipped with numerous sensors that enable us to sense our surroundings and the state of our body. If this information can be reliably recorded, it is possible to use these <u>natural sensors</u> to provide feedback signals to an FES system. The technical problems of recording the information have been substantial because of the small size of the nerve fibres and the low amplitude of the signals that is to be recorded compared to the noise introduced by stimulation of muscles nearby.

US Patent 4,750,499 by J.A. Hoffer described an FES system for partially restoring the motor function of a person having paralyzed mucles, said method comprising implanting a force sensor comprising a nerve electrode for sensing electrical signals primarily from mechanoreceptors associated with a peripheral sensory nerve that supplies glabrous skin of the person having the paralyzed muscles, sensing electrical signals via said force sensor, producing an electrical control signal for activating a muscle stimulator in response to the electrical signals sensed by said nerve electrode, and stimulating the paralyzed muscles in accordance with said control signal. In a practical implementation of this system artifacts such as stimulation artifacts and muscle responses due to the stimulation will, however, be superimposed on the electroneurogram (ENG) signal. If the nerve cuff electrode must be located in close proximity to stimulated muscle, as may often be the case, the ENG signal will most likely be so disturbed that the proposed system can not function.

In an attempt to reduce the noise introduced by stimulation of muscles nearby, Knaflitz and Merletti (1988) have developed a device which features the following: a)  a

"hybrid" output stage, optical isolation of both the stimulation output stage and of the input amplifier stage, monophasic or biphasic stimulation output, artifact suppression obtained by slew rate limiting in the isolated stage and signal blanking in the ground referred stage, and single and double differential detection of the myoelectric signal." However, this has not been a useful approach as the switches in most cases created more noise than was removed when applied to the high gain (>100000) amplifiers used in their study.

DESCRIPTION OF THE INVENTION

A main aspect of the present invention relates to a method for at least partially restoring the motor function of a partially or completely paralyzed muscle, said method comprising implanting a nerve electrode for sensing electrical signals from a sensory nerve which innervates a part of the body which is physiologically related to the partially or completely paralyzed muscle, stimulating the paralyzed muscle by means of a muscle stimulator, sensing by means of said nerve electrode an electrical signal from the sensory nerve, producing a further control signal for reactivating the muscle stimulator dependent on the electrical signal sensed after the expiration of a predetermined period of time after the stimulation of the muscle, and restimulating the paralyzed muscle in response to said further control signal.

An important feature of the present invention is that during a predetermined period of time after the stimulation of the muscle or muscles, essentially no electrical signal is sensed from the sensory nerve, i.e. the further control signal for reactivating the muscle stimulator is dependent only on the electrical signal sensed after the expiration of a pre-determined period of time after the stimulation of the muscle or muscles. The objective of this is to avoid or minimize the artifact contamination by the electromyogram (EMG) on the ENG

signal. Examples on how this can be acomplished are described in more detail in the following.

The invention can also be described as a FES system for at least partially restoring the motor function of a human having at least one partially or completely paralyzed muscle, said system comprising a stimulator means for stimulating the paralyzed muscle or muscles, an implantable nerve electrode for sensing electrical signals from a sensory nerve which innervates a part of the body which is physiologically related to the partially or completely paralyzed muscle or muscles, and
control means responsive to the electrical signals sensed from said sensory nerve after the expiration of a pre-determined period of time after the stimulation of the muscle or muscles for producing a further control signal for re-activating said stimulator means.

In a presently preferred embodiment, the invention relates to a FES system as described above wherein said control means comprises means for amplifying, band-pass-filtering, and optionally rectifying and bin-integrating the sensed electrical signal and means for producing said further control signal in response to said bin-integrated electrical signal. As an example, the bin-integration in the FES system according to the invention can be performed by means of an integrator having an adjustable integration period, said integrator being synchronized with the stimulator means.

More than one partially or completely paralyzed muscle can be stimulated by the method or FES system of the invention. In a particular embodiment which is described in more detail in Example 1, the recording cuff was placed on the tibial nerve and the four plantarflexor muscles were stimulated in turn by the computer. The present invention thus also provides a method for at least partially restoring the motor function of several partially or completely paralyzed muscles, said method comprising implanting a nerve electrode for sensing

electrical signals from a sensory nerve which innervates a part of the body which is physiologically related to the partially or completely paralyzed muscles, stimulating one of the paralyzed muscles by means of a muscle stimulator, sensing by means of said nerve electrode an electrical signal from the sensory nerve, producing a further control signal for reactivating another muscle stimulator dependent on the electrical signal sensed after the expiration of a predetermined period of time after the stimulation of the muscle, and restimulating another paralyzed muscle in response to said further control signal. In an alternative embodiment, several partially or completely paralyzed muscles may be stimulated simultaneously, the further control signal for reactivating the muscle stimulator or muscle stimulators being dependent on the electrical signal sensed after the expiration of a predetermined period of time after the first stimulation of the muscles. In further embodiments, the method may comprise more than one nerve electrode coupled to one or several muscle stimulators, i.e. the method may comprise the combination of two or more FES systems of the invention working together independently or integrated e.g. by means of a computer in an appropriate way.

A suitable nerve electrode for sensing electrical signals from a sensory nerve can be e.g. a cuff electrode implanted around a peripheral sensory nerve. In such a cuff electrode, which may be a split cuff or a spiral cuff electrode, the stability of the recorded signal is stable enough to be used in a FES system. Also other suitable nerve electrodes such as intrafascicular or intraneural electrode (Hoffer and Haugland, 1992) may be used in the method or FES system of the invention.

In a presently preferred embodiment, the method according to the invention is a method wherein the electrical signal is amplified, band-pass-filtered, and optionally rectified and bin-integrated when producing said further control signal.

The bin-integration can be performed by means of an integrator having an adjustable integration period, said integrator being synchronized with the muscle stimulator or muscle stimulators. The sensed electrical signal is generally integrated into a single value to produce the further control signal.

Within the scope of the present invention are also methods wherein the EMG artifact is minimized by other methods such as subtracting the EMG signal recorded by other, nearby electrodes from the ENG signal prior to the processing by the method of the invention. By the use of such further methods for artifact suppression, the predetermined time period during which essentially no electrical signal is sensed from the sensory nerve can be minimized.

In a presently preferred embodiment, the part of the body innervated by the sensory nerve comprises a skin area. However, it is contemplated that the method of the invention will also be useful when the part of the body innervated by the sensory nerve comprises nerves from proprioceptors such as muscular spindles, Golgi tendon organs or joint receptors.

The muscle stimulation may be acomplished by any suitable muscle stimulator. For a review, see e.g. Agnes and Creery, 1990. Also other stimulators with appropriate features can be used in the method of the invention.

Generally, for human applications it is presently preferred that the stimulation signals should be generated at a frequency of about 5-50 Hz, more preferably about 10-20 Hz. The muscle restimulation provided by the further stimulation control signal can be varied e.g. by adjusting the amplitude of the stimulation pulses. Also, the pulse width of the stimulation pulses can be varied. In the presently preferred embodiments, the pulse width of the stimulation pulses is in the magnitude of about 100 - 300 microseconds, such as 150 - 250 microseconds, e.g. 200 microseconds. Also the frequency

of the stimulation of the muscle or muscles may be varied. However, in a simplified embodiment of the method of the invention, the frequency of the stimulation of the muscle or muscles is substantially constant.

Based upon the information in the present specification and claims, it will be within the skill of the person skilled in the art to determine a suitable predetermined period of time after the stimulation of the muscle during which essentially no electrical signal should be sensed from the sensory nerve. This period will of course vary depending on the diagnosis of the patient, the particular paralyzed muscle or muscles which are stimulated, the distance and orientation between the nerve electrode and the muscle stimulator, the type of the stimulation electrodes, the maximum current needed for stimulation etc. Generally, the period is contemplated to be about 3-10 ms or in certain circumstances even less or more after the stimulation of the muscle. As a starting point, it is proposed that the time period is set to be about 5-7 ms.

Example 1 describes a cat model to validate reduction of artifacts by the method of the invention, and Example 2 describes a simple FES system for correction of footdrop in a hemiplegic spastic male.

The technique used in the present invention is shown schematically in Figure 1A. A nerve electrode such as a tripolar cuff electrode, is implanted on a sensory nerve that innervates the part of the body of interest, e.g. skin, joint(s) or muscle(s) or a combination thereof. A differential amplifier (AMP), with high common-mode rejection and a gain between 0.1 million and 1 million, amplifies the signal recorded from the center and the two connected end-electrodes. The amplifier has a bandwidth from 500 Hz to 10 kHz, comparable to the bandwidth of the nerve signal. This signal is then rectified in a full-wave active rectifier (RBI). When nearby muscles are stimulated, this signal unavoidably contains large peaks of stimulation artifacts (if

surface stimulation is used, the stimulation pulses will typically have an amplitude of 100 V, whereas the recorded nerve signal is in the order of 1 μV).

After amplification of the signal from the nerve cuff electrode, further processing is necessary to remove noise and artifacts, produce a signal that represents the overall activity in the nerve, and change that signal into a control signal to the stimulator. An example of a circuit to do this has been implemented for a portable foot-drop correction system, based on analog components.

The circuit consists of the following parts as shown in the block diagram (Figure 1B):

HP-filter

This high-pass filter is mainly necessary because of possible offset voltages from the amplifier that supplies the circuit with information from the electrode. However, since there might be some unintended muscle activity in the recorded signal, the cutoff frequency has been set high, to approximately 600 Hz.

Active rectifier

After the high-pass filter, the signal is now without DC offset and is then full-wave rectified, as the first stage of producing an envelope of the nerve signal. The rectifier is active, i.e. it does not lose information because of a diode-voltage drop for negative values, as would a passive rectifier.

Bin-integrator with timing circuit

In the present embodiment the bin-integrator is the key part of the artifact removal scheme. It consists of an integrator that can be reset, as controlled by an external

synchronization signal and the timer circuit being part of the integrator. When a muscle is electrically stimulated, the stimulator sends a synchronization signal to the bin-integrator. This signal is high for typically 100 $\mu s$ during each stimulus. During this time, the input to the integrator is disconnected by U4A (see Figure 1C), resulting in the value on the output of the integrator being kept constant. When the synchronization signal ends, it starts a timer (U3A on the circuit diagram) (Figure 1C) that short-circuits the capacitor in the integrator (C3). The timer is adjustable up to 27 ms. During this period, that is adjustable in duration by P2, the integrator is reset, and thus ignores the signal. The timer is normally adjusted to time out right after stimulation artifacts that contaminate the signal have died out. Then the integrator starts to integrate during a period which the signal contains only neural information without artifacts until a new synchronization signal appears from the stimulator. During the time the integrator output is kept constant, the switches U4C and U4D connect it to the hold-circuit made up by C4 and U2C, thereby storing the final value of the integration. The sequence of these values is usually referred to as the rectified, bin-integrated ENG, or just RBI-ENG, and is a direct measure of the overall activity in the nerve.

Bandpass filter

It is necessary to process further the RBI-ENG to produce a control signal for the stimulator. In the present embodiment, the first step is band-pass filtering to produce a smooth signal that would reflect overall changes in the nerve activity rather than the absolute activity. This is done by cascading two passive first order filters - a lowpass section (R10 and C7) with a cutoff frequency of approximately 20 Hz, and a highpass section (C5 and R20) set at approximately 1 Hz. An inverting amplifier with gain = 10 then follows because of loss of signal amplitude in the passive filters.

Active rectifier

Usually the fastest changes in nerve activity are increases (as when the heel strikes the floor), but sometimes a decrease could give the most prominent peak in the highpass filtered or differentiated nerve activity. To increase detection reliability, both the positive and negative peak are used for detection by rectifying the signal first. Again, the rectifier is active in order not to lose information because of diode-voltage drops.

Comparator

After highpass filtering and rectification, heel-strike can now be detected by simple threshold detection.

Timer

In the present example, a timer that starts at heel-strike and times out after a time that corresponds to the duration of the stance phase has been employed. In this way the information obtained when the heel hits the floor has been used. The timer controls a transistor that switches the stimulator on and off (which is a commercially available unit). The stimulator is turned on when the timer runs out (estimated time of foot lift) and off when the heel hits the floor (which then initiates a new cycle). The timer is adjustable up to 2.7 s. This system might be modified to use the information obtained when the heel is lifted from the floor.

The analog circuit described above is based on a digital implementation, using a digital signal processor (DSP) (TMS 320C35) placed on a plug-in card in a IBM-compatible personal computer. The circuit was thus implemented as an analog circuit as at that time it did not seem practically possible to make a small DSP card for a portable unit. It is contemplated, however, that in the near future it will be

possible to adapt an existing portable DSP system that will be able to perform the same function and other functions as well.

The circuit presented in Figure 1C is implemented using standard analog components. However, the size can be drastically reduced by using surface mounted components (SMD), as the present inventors have done with the amplifiers that have been constructed. Furthermore, there seem to be no major problems in implementing a digital version on a custom-designed chip (ASIC) that would include both the amplifier for the neural signals, the electronics described here for control of a stimulator, and the stimulator itself. This has been done by others for more simple stimulators (see e.g. Agnes and Creery), which has made it possible to mount all the components inside a biocompatible case and implant this in the body.

In summary, to remove the artifacts described above, the rectified signal is thus bin-integrated in such a way that the noise-free signal in-between stimuli is integrated into a single value by means of a switched integrator and sample-and-hold circuit controlled by the stimulation or alternative analog or digital methods as described above. Contamination by stimulation artifacts was reduced by sampling the ENG only during periods <u>in-between</u> artifacts. The resulting signal, which corresponds to the smoothed envelope of the nerve signal, or in other words, the overall activity in the nerve is then processed (LOGIC), after which it can be used as <u>a feedback signal</u> for the stimulator (STIM).

Another method for suppression of a stimulation artifact could be to blank it out by either disconnecting or short-circuiting the recording electrode during and for some time after the stimulus. In principle this would work if noiseless switches were available. However, in experiments performed by the present inventors with currently available switches,

these proved to be unacceptable because of additional switching noise. The method of the invention only requires that the first stage of amplification has a short recovery-time after eventual saturation. It is contemplated that a recovery-time in the range of 0-2 ms will be preferred, but recovery-times up to about 5-7 ms or even more will be acceptable - depending on the frequency of muscle stimulation.

Due to the larger distances that can be obtained between stimulation electrodes and a nerve cuff electrode it can be expected that in human FES systems, the artifact problems may be smaller than those presented in the cat model (see Example 1). On the other hand, human muscles can be larger than cat muscles, and the number of muscles stimulated in a FES system of the invention may be much larger than four, which may increase the number of artifacts. However, as long as there is at least 10 ms between any two stimuli, it should be possible to sample noise-free ENG. This can be obtained if groups of muscles are stimulated simultaneously rather than in a random or time-distributed manner. In human applications, it is also likely that the stimulation frequency will be lower than the 25 Hz per muscle used for the cat experiments, thereby leaving longer artifact-free periods between the consecutive stimuli.

Among several restorative applications that can be envisioned, two, in particular, could in principle be implemented readily: control of hand function in quadriplegic or hemiplegic persons, and control of stance and gait in paraplegic or hemiplegic persons.

Electrical stimulation of the peroneal nerve, used for correction of a drop-foot has become an established therapeutic and functional method. The stimulation is applied during the swing phase of the affected leg and prevents drop-foot, so the patient walks faster and more securely. The use of the natural tactile information recorded from nerves supplying

the foot can make it possible for the patient to walk without wires running from an external heel contact sensor to the stimulator. Using the distinct peak that appears in the sural ENG signal at heel-contact and the method of the invention, it has been possible to control a drop-foot stimulator during walking (see Example 2). The distinct neural peaks are contemplated to relate to pressure changes on the skin and associated stretches of the skin mechanoreceptors in the skin area that is innervated by the sural nerve.

The human fingertip has a great capability to detect slips between an object and the surface of the skin. Surface features protruding a few micrometers from the surface of an object can be discriminated when stroked along the surface of the skin and small slips involving only a part of the skin surface in contact with an object held in a precision grip can be detected (Johansson and Westling, 1987). This capability originates from the large number of low threshold mechanoreceptors in the skin of the fingertips (as many as 241 units/$cm^2$ (Johansson and Vallbo, 1979)). The information from these receptors is important for the control of precision grip; if the skin is anaesthetized, the subject becomes incapable of adequately adjusting the grip force to the weight and surface structure of an object (Johansson and Westling, 1984).

During precision tasks, normal subjects usually produce grip forces barely greater than the minimum force required to hold an object (Johansson and Westling, 1987), which is determined by both the weight of the object and the frictional properties of the surface in contact with the fingers. If the grip force is insufficient and the object starts to slip, most low-threshold merchanoreceptive units respond with sharp bursts of activity. Slips may happen if the grip force changes as a consequence of changing joint angles or fatigue, if the weight of the object increases (e.g. a coffee cup that gets filled) or if the frictional coefficient decreases (e.g. caused by perspiration). In normal human subjects it has been

shown that a short-latency spinal reflex of cutaneous origin is usually elicited by such a slip, so that within 80 ms of the start of a slip, the grip force increases and the object is held securely again (Johansson and Westling, 1987). This rapid corrective response is automatic, and does not involve conscious participation by the subjects. The reflex action is quite powerful, to the extent that subjects often cannot voluntarily release their grip slowly to let an object fall, because the reflex tends to interfere (Johansson and Westling, 1987).

The cumulative activity of cutaneous merchanoreceptors can be recorded with a nerve cuff electrode (reviewed by Hoffer, 1990) and is presumed to be adequate for feedback control of a system for functional electrical stimulation (FES). The relation between the electroneurogram (ENG) obtained from a nerve cuff implanted on a sensory nerve and the force applied perpendicularly on the skin innervated by the nerve was identified, but contained some inherent non-linearities that made it difficult to use the ENG for estimation of the perpendicular skin contact force. The sensitivity of the cutaneous mechanoreceptors to slips occurring between the skin and an object suggests that the ENG may contain a different, and possibly very useful, kind of information other that just information about perpendicular skin contact force. The possibility of extracting slip related information from the ENG recorded with a nerve cuff electrode and its possible application in an FES system for hand grasp is a central feature of the present invention. With reliable slip information available, an FES system implementing an "artificial gripping reflex" should enable a paralysed hand to hold an object with only the necessary force and maintain a good grip even if the muscles fatigue, if skin-to-object friction changes or if the weight of the object changes. A different version of an "artificial gripping reflex" has previously been implemented for the control of <u>prosthetic</u> hands, where the incipient slip of an object being held by an

amputee in a prosthetic hand was measured and used to control the force of prehension (Colman and Salisbury, 1967).

Our experimental model of a hand grasping and lifting an object was the foot of an anaesthetized cat pressing against an object that would slide down if the force exerted by the foot was insufficient to hold the object in place. The force was produced by stimulation of the plantarflexor muscles via intramuscular electrodes, using a computer controlled FES system. Slip information extracted from the tibial ENG was used to compensate for slip occurring in two different experimental situations: When muscle activation declined and the grip force fell below the minimum level required for a secure grip or when the weight of the object increased suddenly while being held with a constant grip force, causing the object to move.

The findings made in connection with these experiments gave rise to another important main aspect of the present invention. This aspect of the invention relates to a method for providing a secure grip of an object through FES of a partially or completely paralyzed muscle which is involved in holding the object, comprising

implanting a nerve electrode for sensing electrical signals from a sensory nerve which innervates a part of the body which is physiologically related to the partially or completely paralyzed muscle,

detecting the start of a slip of the object from the ENG signal from the nerve electrode,

and immediately upon detection of the start of a slip producing or modifying a control signal for activating a muscle stimulator and stimulating the paralyzed muscle in response to said control signal.

The start of the slip may, e.g., be caused by an external change in the load or weight of the object, or by an internal disturbance such as fatigue, or it may be caused by a change in the frictional coefficient of the skin, such as due to sweating.

As will be explained in greater detail in the following, the start of the slip is preferably detected automatically as an event that exceeds a predetermined threshold value. A suitable way of doing this is where the ENG recorded from the sensory nerve is processed using analog or digital circuitry, and a filtered version of the ENG is subtracted from the actual electrical signal sensed, thereby removing unrelated background activity from the signal, the resulting calculated signal being identified as a signal related to the start of a slip if it exceeds a predetermined value. The filtered version of the ENG, such as a low pass-filtered version, is suitably delayed by a number of samples and then subtracted from the actual signal sensed. The actual signal which may or may not represent a "start of slip-related signal", is suitably an unfiltered signal or a signal which has been subjected to filtering with a shorter time constant than the first-mentioned filtered version.

Further details concerning this aspect of the invention are given in below:

Signals from cutaneous mechanoreceptors were recorded with a nerve cuff electrode implanted on the tibial nerve of cats. These signals can be related to the perpendicular skin contact force applied on the central footpad. The signals can also be recorded during functional electrical stimulation (FES) and therefore may be used as feedback for an FES system appropriate for restoring motor functions in patients paralysed by, for example, a spinal cord injury or stroke.

Example 3 describes how slip-related information was derived from the cutaneous electroneurogram (ENG). This information was used in an event-driven controller for precision grip that allowed the FES system to compensate for unexpected slips between an object and the skin. In this way an "artificial gripping reflex" was implemented that compensated automatically for internal changes (fatigue) and external perturbations (increased load, changing frictional coefficient). This control scheme proved to be robust, and is presumed to be applicable for restoration of precision grip in paralysed humans using FES.

The information recorded with a nerve cuff electrode implanted on a cutaneous nerve can be used reliably for feedback control in a FES system. This approach could have direct applications for the restoration of precision grip in spinal cord injured patients (e.g. C4-C6 quadriplegic;, where it could be used to implement an "artificial gripping reflex" similar to the natural gripping reflex that is present in normal humans.

The system of the invention reliably detected slips from the recorded ENG, in situations where the slips occurred either because of decreasing grip force or because in increased load force. The grip was fully regained by issuing a pulse doublet to each of the four muscles, combined with a 25-30% increase in the duration of subsequent pulses. The resulting grip force closely resembled that of humane when adjusting to a sudden increase in load force (Johansson and Westling, 1988) by increasing rapidly to a high value and the settling at a value somewhat high than before the load change. The time between the object first started to move and slip detection was in the range of 50 to 100 ms. Typically, for slips caused by our "fatigue" paradigm, the object moved less than 3 mm before it was caught, and for slips caused by a sudden increase in load the object moved less than 4 mm before it was caught. The method proved to be equally robust in all three cats used in this study.

Only one parameter (the threshold value) in the slip detection algorithm needed initial adjustment at each day of experiment, although it did not need any further changes for the rest of the recording session (that usually lasted 4-6 hours). The threshold parameter could be increased by more than 50% of its optimal value without seriously effecting the detection of slips. Once set, the threshold value needed no other adjustment during the rest of the experiments that day.

The increment in the stimulation intensity after slip was set to 25-30% in the present experiments, which proved necessary and sufficient to secure the grip in these specific situations. In a clinical FES system, the optimal value of this factor will depend not only on the instantaneous recruitment curve for the stimulated muscle(s), but also on the reasons for slips, e.g. how the weight of the object has changed, how strong a perturbation was, as well as a number of other factors, such as the fragility of the object. It is anticipated that this value may be easily adjustable by the user, to fit the exact conditions of his/her muscles, temperament, and FES system.

In addition to enabling an FES system to compensate for declining grip force or external perturbations, slip information may also be used for an initial determination of the optimal stimulation intensity, and thus avoid causing muscle fatigue from using unnecessarily strong stimulation. The stimulation scheme shown in Fig. 8, i.e., a slowly decreasing intensity combined with slip detection and compensation, automatically determines the minimum necessary intensity to hold an object and to adjust to slowly varying load changes, or it may just be used initially to determine a suitable intensity that is then held constant unless and until other slips occur.

In the intact human, information from skin receptors is essential for the regulation of force during precision grip. Visual cues such as size, material and surface structure play

a role in deciding the initial forces when gripping and lifting an object, but for the steady-state holding phase, the somatosensory information from the skin effectively defines the necessary force with no apparent relation to pre-lift visual cues. The results reported here suggest that an FES system for precision grip in paralysed humans could use the same cutaneous afferent information as the intact organism and implement a similar control strategy, thereby adjusting the grip force automatically to the weight and surface structure of the object in hand in the form of an "artificial gripping reflex".

In paralysed humans, tactile information arising from the thumb, index and/or middle fingers could be recorded with nerve cuff electrodes, either from the palmar cutaneous branch of the median nerve proximal to the wrist, or from individual internal digital nerve branches in the hand. Experiments with a nerve cuff implanted on the median nerve of a monkey (Milner et al., 1991) have produced ENG signals during perturbations of precision grip that closely resemble those represented in the cat experiments by the present inventors suggesting that the median nerve may be a suitable source of the desired signal.

For the restoration of gait and stance in persons impaired by paraplegia or stroke, cutaneous feedback information originating from mechanoreceptors in the soles of the feet could be recorded with nerve cuff electrodes implanted on the internal and external plantar branches of the posterior tibial nerve, and the sural nerve. The tibial nerve branches contain afferents from the medial and lateral aspects of the ball of the foot, and the sural nerve contains afferents from the heel. To avoid mechanical damage to the nerves or cuff electrodes, the electrodes would best be installed proximal to the ankle, rather than in the foot.

In stroke patients who may require only electrical stimulation of the peroneal nerve to control ankle dorsiflexion

during the swing phase, a single sural or tibial nerve cuff would be sufficient to monitor whether or not the affected foot is supporting weight. Recordings from the sural nerve in man (Sinkjær et al., 1991) has demonstrated a distinct peak in the nerve signal at foot contact. In partially or complete paraplegic patients, where the coordinated activation of both legs must be restored, three cuff recording electrodes in each leg would provide information on mediolateral and anteroposterior weight distribution on each leg, as well as on timing of foot contact and inter-limb load distribution, considered essential for successful restoration of gait with FES. Although such information can be obtained with external pressure sensors placed inside shoes, inherent problems of calibration, mechanical and electrical drift, lead breakage, and sensitivity to environmental factors like moisture and temperature, that affect external transducers, would be avoided if nerve cuff electrodes were used. Because satisfactory restoration of gait often cannot be achieved using FES alone, individual solutions are likely to involve FES-based hybrid systems tailored to the specific pattern of sensorimotor deficit presented by each patient.

For hand control applications, the tactile feedback recorded from the median nerve or from its branches would regulate the output of a portable multichannel FES system to control several types of grip by stimulating forearm and hand muscles via, e.g., permanently implanted epimysial electrodes. To avoid risks associated with transcutaneous passage of leads, it would be preferable that both the nerve recording and the muscle stimulation information would be telemetered across the skin. The command signals for the FES system would be generated by the user, using unaffected motor functions. In initial applications, regulatory feedback would be implemented to use slip information to automatically update the stimulation parameters. To also implement continuous regulatory feedback, appropriate algorithms would have to be available to extract moment-to-moment information on grip force or other relevant parameter, from the ENG signal.

The principle of the present invention may also be useful in other applications where physiological signals must be sampled during stimulation of nearby muscles, e.g. in FES systems using the EMG from intact or partially intact muscles or ENG from efferent nerves as a means to control the stimulator or prothesis.

It is evident that the two above main aspects of the invention can be used independently or combined in order to improve FES methods.

LEGEND TO FIGURES:

Figure 1.

A) Principle for recording and using natural sensory nerve activity from peripheral nerves in a system for functional neuromuscular stimulation. Figure shows as an example a system for restoration of upper limb function, but the principle would be similar for lower limb.

| | |
|---|---|
| 1. | Telemetric coupling between implanted and external equipment |
| 2. | Implanted stimulator |
| 3. | Shoulder position sensor |
| 4. | Stimulation electrodes |
| 5. | External portable control units and batteries |
| AMP: | Amplifier for the neural signal |
| RBI: | Rectifier & bin-integrator (see Figure 1B) |
| LOGIC: | Extraction of information and generation of control signal |
| STIM: | Stimulator |

B) Block diagram of the artifact suppression technique and method to control a footdrop stimulator. The first part, that corresponds to the RBI unit in Figure 1A, is where the artifacts in the neural signal are suppressed. It consists of the highpass filter, rectifier and bin-integrator (see text for details). The second part is specific to the foot-drop prosthesis application, and generates a control signal for the stimulator based on the artifact free nerve signal. This part corrsponds to the LOGIC unit in Figure 1A, and consists of the band-pass filter, rectifier, comparator and timer (see text for details).

C) Example of how the system in Figure 1B can be implemented using standard analog electronics. The parts separated by dashed lines corrspond to the blocks in Figure 1B. The

circuit here has been used in a portable system for footdrop correction. See text for detailed description of the circuit.

Figure 2.

Raw signal recorded from the tibial nerve cuff while nearby muscles were stimulated. Four sweeps of data are shown superimposed. In the top trace, the bandwidth was 65 Hz - 10 kHz, and the EMG volleys were clearly present, whereas in the bottom trace, the signal was high-pass filtered at 1000 Hz and the EMG pickup was practically removed. Horizontal bars show the periods during which the nerve cuff signal was bin-integrated and sampled by the computer.
AS = amplifier saturation
TO = Temporary tape overload due to saturation

Figure 3.

Verification of the artifact removal method. The solid traces show the force (top) and normal rectified, bin-integrated ENG (bottom) during stimulation of the four calf muscles in a cat model under anaestesia. The dashed traces show a similar trial, with the tibial nerve blocked distal to the recording cuff.

Figure 4.

Rectified and bin-integrated (RBI) human sural nerve cuff recordings while tapping with a finger on the skin within the innervation area of the nerve. In the top trace, no electrical stimulation is applied and the nerve signal is not disturbed by artifacts. The middle trace shows the disturbed nerved signal when a 100 Hz stimulation is applied next to the nerve without artifact suppression. The bottom trace shows the nerve signal during the same 100 Hz, but with artifact suppression.

Figure 5.

Diagram of electrodes implanted in cat hindlimb and apparatus used to measure neural responses during grip. The cat was under anesthesia. The limb was fixed at the ankle malleoli and knee with atraumatic, cupped clamps. Forces were produced by FES via electrodes implanted in the four ankle dorsiflexor muscles (MG, LG, Sol and Pl; not all are shown). ENG activity in the tibial nerve was recorded with a tripolar nerve cuff electrode. When the plantarflexor muscles were stimulated the paw moved (curved arrow until the footpad pressed against an object that could slide vertically along a lowfriction bearing. It was covered with fine sandpaper on the surface contacted by the cat's footpad, and contained two force transducers to measure vertical (load) force and horizontol (grip) force, as well as a linear position transducer to measure vertical position.

REFERENCES

Agnes, W. F., MacCreery, D. B., editors, "Neural Prosthesis" in: "Fundamental Studies", Printice Hall, New Jersey, USA, 1990.

Colman, A.B., L.L. Salisbury, *Med. Biol. Eng.* 5, pp. 505-511, 1967.

Gordon, A.M., H. Forssberg, R.S. Johansson, G. Westling, "Visula size cues in the programming of manipulative forces during precision grip," *Exp. Brain Res.*, 83, pp. 477-482, 1991.

Haugland, M.K., J.A. Hoffer, T. Sinkjær, "Skin contact force information in electroneurographic signals recorded by implanted nerve cuff electrodes," *IEEE Transactions on Biomed. Eng.*, (submitted concurrently).

Haugland, M.K., J.A. Hoffer, "Sensory nerve signals recorded by implanted cuff electrodes during functional electrical stimulation of limb muscles," *IEEE Transactions on Biomed. Eng.*, (submitted concurrently).

Hoffer, J.A., "Techniques to study spinal-cord, peripheral nerve, and muscle activity in freely moving cats," *Neuromethods*, Vol. 15, pp. 65-145, 1990.

Hoffer, J.A., Haugland M. and Li, T. Obtaining skin contact force information from implanted nerve cuff recording electrodes. *Proc. IEEE Eng. in Med. & Biol. Soc. Intl. Conf. 11:* 928-929, 1989.

Hoffer, J.A., Haugland, M. and Sinkjær, T. Functional restoration of precision grip using slip information obtained from peripheral nerve recordings. *Proc. Ann. Intl. Conf. IEEE Eng. in Med. & Biol. Soc. 13*:896-897, 1991.

Hoffer, J.A. and Haugland, M. Signals from tactile sensors in glabrous skin suitable for restoring motor functions in paralyzed humans. In: *NEURAL PROSTHESES: Replacing Motor Function after Disease or Disability*, R.B. Stein, P.H. Peckham and D. Popovic, editors. Oxford Univ. Press, pp. 99-125, 1992.

Hoffer, J.A., N. Sugano, G.E. Loeb, W.B. Marks, M.J. O'Donovan, C.A. Pratt, "Cat hindlimb motoneurons during locomotion. II. Normal activity patterns," *Journ. of Neurophys.* vol. 57, no. 2, pp. 530-553, Feb. 1987.

Johansson, R.S., Å.B. Vallbo, "Tactile sensibility i the human hand: Relative and absolute densities of four types of mechanoreceptive units in glabrous skin," *J. Physiol. (Lond)*, 286, pp. 283-300, 1979.

Johansson, R.S., G. Westling, "Roles of glabrous skin receptors and sensorimotor memory in automatic control of precision grip when lifting rougher or more slippery objects," *Exp. Brain Res.*, 56, pp. 550-564, 1984.

Johansson, R.S., G. Westling, "Signals in tactile afferents from the fingers eliciting adaptive motor responses during precision grip," *Exp. Brain Res*, 66, pp. 141-154, 1987.

Johansson, R.S., G. Westling, "Programmed and triggered actions to rapid load changes during precision grip," *Exp. Brain Res.*, 71, pp. 72-86, 1988.

Milner, T.E., C. Dugas, N. Picard, A. Smith "Cutaneous afferent activity in the median nerve during grasping in the primate," *Brain Res.*, 548, pp. 228-241, 1991.

Sinkjær, T., Haugland, M., Haase, J. and Hoffer, J.A. Whole sensory nerve recordings in human -an application for neural prostheses. *Proc. Ann. Intl. Conf. IEEE Eng. in Med. & Biol. Soc. 13*:900-901, 1991.

Vallbo, Å.B., R.S. Johansson, "Properties of cutaneous mechanoreceptors in the human hand related to touch sensation," *Human Neurobiol.* 3:3-14, Springer Verlag, 1984.

Westling, G., R.S. Johansson, "Responses in glabrous skin mechanoreceptors during precision grip in humans," *Exp. brain research*, No. 66, pp. 128-140, 1987.

Zajac, F.E., J.L. Young, "Discharge properties of hindlimb motoneurons in decerebrate cats during locomotion induced by mesencephalic stimulation", *Journal of Neurophysiology*, vol. 43, pp. 1221-1235, May 1980b.

# EXAMPLES

## EXAMPLE 1

### MINIMIZING THE ENG-ARTIFACT SIGNAL GENERATED BY MUSCLE STIMULATION IN A CAT EXPERIMENT

Surgical implantation:

In cats which were surgically anesthetized, a 30-40 mm long, 2.2 mm I.D. silicone rubber cuff with 3 circumferential stainless steel wire electrodes (Cooner AS 631) was implanted on the left tibial nerve, 2-4 cm proximal to the ankle joint. A sciatic nerve recording cuff, 20 mm long, 4 mm I.D. with three stainless steel wire electrodes, was implanted in the mid-thigh region. Leads from the cuffs and other implanted devices coursed subcutaneously to an external connector mounted on the cat's back as described in Hoffer, 1990. After surgery, cats were given analgesics (Acepromazine Maleate and subcutaneous Morphine, 0.10 mg/kg) for at least 24 hr. Recording sessions started 4-7 days after implantation.

Nerve blocking cuffs:

To exclude the participation of motor activity in the ENG recorded from the tibial nerve during walking, in several cats a blocking cuff 8 mm long, was placed on the tibial nerve, between the tibial and sciatic recording cuffs. Axonal conduction was blocked by infusing lidocaine sodium solution (2%), via a catheter that led to the blocking cuff from a port in the external connector. The conduction block was assessed from the progressive reduction of the compound action potential recorded by the sciatic nerve cuff, evoked by stimulation of the tibial nerve at the distal recording cuff. Usually, the tibial nerve was completely blocked after 20-30 minutes. At the end of each experiment the block was reversed with infusion of normal saline solution.

In other cats, a tibial nerve blocking cuff was placed distal to the tibial nerve recording cuff in order to identify the contributions from footpad afferents, and the presence in the recording cuff signal of any artifacts caused by the stimuli and/or compound EMG potentials during FES of nearby muscles.

Data collection:

On average once per week during a 1-3 months period, each cat was anaesthetized with halothane gas, the left foot was shaved, remaining hair was removed with depilatory cream, and the leg was secured at the ankle malleoli and knee with two pairs of cupped holders. In the first series of experiments, a servo-controlled motor was used to push perpendicularly on the central footpad with a 1 cm disc-shaped probe. Applied forces were monitored by a series transducer. The position and compliance of the motor were electronically regulated with position, velocity and force feedback. Control signals were generated with an IBM-compatible '386 computer. The tibial ENG was analog-rectified and bin-integrated in 1-10 ms bins (Bak PSI-1). ENG, motor position and force data were digitized on-line (100 Hz/channel) with the same computer.

Removal of artifacts.

Two steps are used to reduce the amplitude of artifacts from nearby muscle activity (EMG) in the nerve activity (ENG signal): 1) High-pass filtering and 2) Synchronization of sampling and stimulation.

1) The frequency distributions of ENG and EMG recorded by tripolar nerve cuff electrodes are largely non-overlapping. Most of the EMG could therefore be "extracted" from the cuff signal by filtering the signal with a sharp high-pass analog filter at 1000 Hz (Ithaco model 4302, set at 80 dB/decade).

2) Because the times of stimulation were known and both the stimulation artifact and the EMG CAPs were limited in

time, it was possible to reduce the artifact pickup substantially by only using the cuff signal at the end of the inter-pulse interval, i.e. the sampling was locked to the stimulation, resulting in a sampling frequency of 100 Hz.

Figure 2 shows 4 superimposed recordings of the cuff signal during FES. Each record was 40 ms long and thus included 4 stimuli. The four traces were synchronized to the time of stimulation of the soleus muscle. Each time a muscle was stimulated (labelled 'Stim'), the first event in the cuff signal was the stimulation artifact, showing up as a narrow spike that would vary in amplitude depending on the stimulation intensity and the muscle that was stimulated. This was followed by the compound EMG volley from the stimulated muscle, showing up as a slower, large amplitude wave in the cuff signal (labelled E+N). The shape of this EMG burst depended on the stimulus intensity and the muscle being stimulated, but was otherwise very repeatable. The neural signal itself was the higher-frequency signal, 5 $\mu$V in amplitude, onto which the artifacts were added.

The data in Figure 2 were obtained by recording the cuff signal on an FM tape recorder while the computer controlled the stimulation intensity using external force feedback, as described above. The signal was then replayed and sampled at a high rate (20 kHz) to produce the figure. For large positive artifact amplitudes, the amplifier saturated (marked AS) and for large negative amplitudes, the tape recorder overloaded (marked TO) causing the signal to be zero during the overload.
The effects of filtering can be seen by comparing the top and bottom traces in Figure 2. In the top panel, filtered between 65 Hz and 10 kHz, the pickup of the EMG volley showed up very clearly. In the bottom panel, the same signal was further high-pass filtered at 1 kHz, and the EMG contamination was largely removed.

The stimulation artifacts were blanked out by sampling the ENG only during periods in-between artifacts. Periods of artifacts are normally easily located by visuel inspection of the ENG-signal since remains of stimulus-related EMG, direct stimulation artifacts and amplifier recovery are synchronized to the stimulation, which is not the case for the ENG. The bin was defined so that none of these artifacts were apparent within the window. Instead, we used a rectifier/integrator (Bak RBI-1) that had an adjustable integration period and was reset in synchrony with an external clock. This clock was supplied by the stimulator, and it was thus possible to integrate the ENG signal in bins that lasted 3-4 ms and that included only data from the last part of each inter-stimulus interval (horizontal bars in Figure 2). The ENG in each of these periods was rectified and integrated, resulting in a single value for each bin that was sampled just before a new stimulation pulse was elicited.

The validity of this method of noise or artifact suppression was demonstrated by the following experiment. The muscles were first stimulated to generate a force profile shown by the solid trace in Figure 3, top panel. This gave rise to the ENG signal shown by the solid trace in Figure 3, bottom panel. Without changing the setup, conduction in the nerve was then blocked with infusion of 0.4 ml lidocaine to the blocking cuff. After approximately half an hour, the ENG signal recorded from the tibial nerve was insensitive to touching and squeezing of the foot, demonstrating that afferent conduction was completely blocked. The stimulation was then repeated and a similar force profile was generated, (shown by the dashed line in Figure 3, top panel). The sampled cuff signal was now reduced to the flat dashed line in Figure 3, bottom panel, i.e. containing neither ENG, nor stimulation artifacts or EMG. Since the only difference was the blocking of the nerve distal to the recording cuff, this experiment showed that for the unblocked nerve, the sampling method removed all introduced artifacts and only sampled ENG activity.

EXAMPLE 2

FOOTDROP PROSTHESIS IN A HEMIPLEGIC SPASTIC MALE

For the footdrop prosthesis, the neural signal from the sural nerve can be used for detection of foot-contact. Highpass-filtering at 1 Hz followed by rectification and threshold comparison reliably detects when the heel touches the floor during walking. This has been used to switch on and off a commercially available peroneal stimulator (KDC 2000A) and in this way, replacing the usual heel-switch that must be mounted in the shoe with the natural sensors in the skin of the foot.

In the present example, the sural nerve in a 35 year old hemiplegic spastic male subject with a drop-foot was instrumented with a tripolar whole nerve cuff electrode approximately 7 cm proximal and 3 cm posterior of the lateral malleolus of the right ankle joint. A clinical examination had revealed that the patient had an Achilles tendon contracture and tremor around the ankle joint. The subject gave his consent and the study was approved by the Local Ethical Committee.

Surgical procedure

The surgery was performed during local anaesthesia. To prevent compression-neuropathy associated with post-surgical oedema, it was ensured that the inner diameter of the cuff was more than 30% larger than the nerve diameter. The three Teflon-coated multistrand stainless steel lead out wires (Cooner Wire Company, USA) from the cuff electrode were put through the skin approximately 25 cm above the lateral malleolus. The nerve cuff was placed so that the nerve was neither pulled nor torqued by the wires. This makes the long-term prognosis of a nerve preparation excellent.

Nerve cuff electrode configuration

The nerve cuff recording electrode consisted of an insulating cuff (silicone tubing) containing three circumferential metal electrodes (flexible 40-strand stainless steel wire, Teflon-coated), placed around part of the sural nerve. The design, fabrication and surgical implantation of nerve cuff recording electrodes have been reviewed in detail elsewhere (Hoffer, 1990). The insulating cuff serves to resolve the small action currents generated by nerve fibres, by constraining the current flow within a long, narrow resistive path. In this application, the cuff was 3 cm long and had an inner diameter of 2.5 mm.

Neural amplification and stimulation

The leads from the implanted nerve cuff electrode were connected to a differential ENG amplifier with a high common mode rejection. The transcutaneous stimulation was made by means of a reference electrode above the tibialis anterior muscle and an active electrode above the common peroneal nerve just distal to the branching off of the superficial peroneal nerve.

The neural amplifier was battery-supplied and optically isolated from the mains to increase the common mode rejection and to reduce the risk to the subject. To further reduce noise pick-ups, an external reference electrode was placed between the stimulation electrodes and the nerve cuff electrode. The neural signal was fourth-order band pass filtered from 0.7 to 10 kHz (Kron-Hite, model 3750). This would reduce remaining pick-up of 50 Hz from the mains, if any, and the EMG from neighbouring muscles to a negligible level. The bandwidth of the recorded neural signal ranged from 0.2 to 3.0 kHz.

Nerve signal with and without electrical stimulation and with and without removal of artifacts from the nerve signal.

The sural nerve activity in a human subject was recorded while tapping with a finger on the skin within the innervation area of the nerve. Fig. 4 (top) shows the amplified, rectified and integrated (RBI) nerve signal without an electrical stimulation. A clear peak in the nerve signal was observed when the finger touched the skin. Fig. 4 (middle) shows the RBI sural nerve activity when an electrical stimulation every 10 ms (100 Hz) was applied next to the nerve. The electrical stimulation elicited an action potential in the nerve recordings approximately 2 ms after the stimulation with a duration of approximately 2 ms (not shown). Fig. 4 (middle) shows how this unwanted signal increased the recorded activity making it very difficult to detect the nerve responses caused by the finger-tapping. Applying the artifact suppression technique by sampling the nerve signal in a window from 5 to 10 ms after each stimulation, the artifacts were removed and the nerve responses to the finger-tapping were again recognized in the cuff electrode recordings (fig. 4 (bottom)). The rectified and integrated nerve signal in each of the sampled periods after a stimulation resulted in a single value for each bin that was sampled just before a new stimulation pulse was elicited. The artifact suppression is made exactly as described for the cat data in Example 1.

EXAMPLE 3

Slip-detection and compensation in a cat model of human position grip

The hindlimb of anaesthetized cats was used as an experimental model for the paralysed human limb, with the central footpad as a model glabrous skin. Three cats (4-6 kg) were chronically implanted using aseptic techniques,

following the procedures and guidelines described in Example 1.

Bipolar intramuscular stimulation electrodes were implanted in each of four ankle extensor muscles: Medial and lateral gastrocnemius (MG, LG), soleus (Sol) and plantaris (Pl). The electrodes consisted of two Teflon coated, 40-strand stainless steel wires (Cooner 634), with the ends deinsulated for 15 mm, and were inserted in the muscle diagonally to the fibres, about 2 cm apart in the proximal part of the muscle (see Fig. 5). Bipolar stimulation electrodes were used, rather than monopolar with respect to a common ground, because of the higher selectivity attained.

A tripolar nerve recording cuff (30 mm long, 2.2 mm I.D.) was implanted on the tibial nerve, distal to the muscular branches, and 4-5 cm above the ankle. At this level, the tibial nerve contains mainly afferent fibres, mostly from the plantar surface of the foot and the footpads, and the cuff could be implanted without obstructing the blood supply to the nerve or causing mechanical damage to the nerve.

The cats recovered for at least 3 days after surgery before the first experiment was performed, in order for the implanted devices to stabilize within the leg. At the beginning of each recording session, the cat was anaesthetized with an intravenous injection of Thiopentothal (8-10 mg/kg) through a catheter implanted in a superficial jugular vein, intubated and maintained under anaesthesia with Halothane in a mixture of nitrous oxide and oxygen.

To remove sensory afferent contributions from hair receptors in the skin surrounding the central footpad, prior to each experiment the foot was shaved and treated with depilatory cream, followed by a thorough wash and application of moisturizing cream.

During an experiment, the cat was supported by a heated sling, with the implanted hindlimb fixed by two pairs of cupped clamps pressed around the ankle and knee joints (Fig. 5). This allowed the ankle joint move and did not do serious damage to the skin. The ankle and knee angles were 100°. The foot hung vertically when not stimulated. When the ankle extensor muscles were stimulated, the footpad pushed horizontally against a test object that could slide vertically with low friction along two bars, and that would fall if held by the foot.

In analogy to the precision grip experiments by Westling and Johansson (1987), the object was equipped with force sensors that measured the horizontal grip force and the vertical load force by means of strain-gauge force transducers (Revere, FT50). The vertical position of the object was measured with a mechanical linear position transducer (Waters, LRT-S-100B) (Fig. 5). Gravity caused a constant downwards pull of 1.4 N, since the object weighed about 140 grams. The surface of the object was 600 grit sandpaper.

The stimulator we used for FES was the same as in Example 1, produced rectangular monophasic constant current pulses with a fixed amplitude for each channel. Pulse widths were independently controlled for each of the four muscles between 0 and 255 $\mu$s, in steps of 1$\mu$s, by a '386 computer via a parallel port. Each muscle was stimulated at a fixed frequency of 25 Hz, i.e. with interpulse intervals of 40 ms. To reduce force ripple caused by unfused tetani, the four muscles were stimulated sequentially, so that one of the muscles was stimulated every 10 ms, giving an aggregate stimulation frequency of 100 Hz, e.g. the same as described in Example 1.

The ENG signal recorded from the tibial nerve was filtered (1k-10 kHz bandpass), rectified and bin-integrated (in one 3 ms bin every 10 ms) before sampling. This procedure was used to cancel out the pickup of artifacts as described in Example

1, and also allowed the use of a lower sampling frequency (100 Hz) that the frequency necessary to sample the raw ENG (20 kHz). The bin-integrator and sampling were synchronized to the delivery of stimulation pulses by the computer. In this way the ENG envelope was sampled at the same frequency as the aggregate stimulation rate (100 Hz). In the following the term "ENG" will refer to the <u>envelope</u> of the ENG rather that to the raw ENG, since only the envelope was sampled for feedback purposes.

*Results*

To investigate slip-related information contained in the ENG signal, the following initial experiments were done: The four plantarflexor muscles were stimulated with a train of pulses of constant width, thus generating a force that was approximately constant. The pulse width was chosen so that the generated force was not sufficient for the foot to hold the object in place. Under these conditions, the object had to be partially supported by the experimenter, who could thus allow it to fall by releasing its support in small steps, each step causing a slip between the paw and the object as described in Hoffer and Haugland, 1992.

The sharp bursts of ENG activity that signalled when slips occurred were typical for all experiments and for all cats used in this study. Slip-related bursts were distinct enough from the background ENG to be detected with great accuracy, and very early in the slip phase.

The sharp bursts of ENG activity that signalled when slips occurred were typical for all experiments and for all cats used in this study. Slip-related bursts were distinct enoguh from the background ENG to be detected with great accuracy, and very early in the slip phase.

A. Detection of slip

Since slips were accompanied by ENG bursts, they could be detected comparing the differential ENG to a threshold value. Simple differentiation, through, calculated as the difference between the present ENG value and an old ENG value, proved too noisy. Instead, a "slip detection" signal was calculated by subtracting a low-pass filtered (time constant = 0.2s) version of the ENG signal delayed by 20 samples (200s) from the 'unfiltered' ENG, thereby removing the background activity from the ENG. The 'unfiltered' ENG also needed some filtering to reduce noise, but this was done with a shorter time constant (0.07s). The set of time constants, delay and threshold value gave the most sensitive and robust slip detection were found by trial and error.

Implementation of the detection algorithm was done in C (Turbo-C 2.0, Borland), and the filters were implemented as first order auto-regressive (AR) filters, which are computationally very simple. The algorithm to detect slip is shown below:

```
    repeat (this loop runs at 100 Hz)
Update 20 samples of old ENG values
Sample new ENG value
BackgroundENG=BackgroundENG*α+OldENG*(1.a)
SlipENG=SlipENG*b+NewENG*(1-b)
SlipDetect=SlipENG-BackgroundENG
if SlipDetect>Threshold then signal that a slip occurred
    end
```

The constants a and b were determined from the time constants discussed above (for □=0.2s--> a=0.951 and □=0.07s--> b=0.867). Within the algorithm, the muscle stimulation intensities were also determined and pulses were elicited by the computer, as described below.

B. Increase of force after slip

As soon as a slip was detected, the force was increased as fast as possible to reestablish a secure grip of the object before it moved out of reach. This was done by one of the following two different methods: 1) By introducing immediately a single, closely spaced pair of stimulation pulses ("doublet") to each of the four muscles. This is a technique that is also used by the central nervous system in normal conditions and can cause the force to not only increase rapidly, but also remain high for a prolonged period after an extra pulse. The time between the two pulses was set to 5 ms. 2). By increasing the pulse width markedly for a short period after the slip, in order to recruit more motor units.

Once the grip was re-established, it was maintaimed by increasing the pulse width moderately (relative to the original PW). With this approach, the grip force changes closely resembled those seen in humans during the adjustment to sudden increases in load force (Johansson and Westling, 1988).

Because the ENG was sampled at 100 Hz, a maximum of 10 ms could elapse between the detection of a slip from the ENG and the response from the controller. Since the ENG was sampled just before each stimulus pulse was elicited, the fastest response to a detected slip was determined only by the time it took to do the calculations (less than 1 ms). The main delay in the slip detection was caused by the low-pass filtering of the ENG that was necessary to remove false detections caused by normal variations in the ENG. The time-constant for this filter was 70ms, as described above. The delay from the moment the object first started to slide down until the slip was detected was between 50 to 100 ms, but varied considerably.

A doublet pulse caused the next ENG sample to contain additional stimulus artifact, but this was not a problem, because

once the controller was switched into "slip compensation mode", it did not require or expect valid samples for the next 300 ms. This prevented erroneous detections of slip during rapid in increases in stimulation intensity, which predictably gave rise to phasic ENG bursts that could resemble those caused by a slip.

The stimulation algorithm included an automatic shut-off of stimulation in the object dropped out or range, determined by monitoring the signal from the vertical position transducer.

C. Test of closed-loop slip compensation controller

Two sets of experiments were done:

1) In experiments that simulated progressive "fatigue" in the stimulated muscles, the stimulation started at a level higher that the minimum necessary to hold the object. The intensity of stimulation was then decreased at a constant rate, until the force became insufficient to hold the object, which then started to slip. Detection of the slip triggered the controller to increase the intensity and grasp the object as detailed in the preceding section, i.e. an "artificial gripping reflex" was elicited. The intensity of stimulation was then slowly decreased at the same rate as prior to the slip.

2) In experiments that modeled the response to increases in external load, the stimulation intensity was held constant at a level sufficient for the foot to hold the object. After a fixed time, an extra load was dropped on the object, causing the object to slip and start to fall. The "artificial reflex loop" caused the slip information obtained from the neural signal to increase the stimulation intensity and thus also the grip force, in order to catch the object before it fell.

CLAIMS

1. A method for at least partially restoring the motor function of a partially or completely paralyzed muscle, said method comprising

implanting a nerve electrode for sensing electrical signals from a sensory nerve which innervates a part of the body which is physiologically related to the partially or completely paralyzed muscle

stimulating the paralyzed muscle by means of a muscle stimulator

sensing by means of said nerve electrode an electrical signal from the sensory nerve

producing a further control signal for reactivating the muscle stimulator dependent on the electrical signal sensed after the expiration of a predetermined period of time after the stimulation of the muscle, and

restimulating the paralyzed muscle in response to said further control signal.

2. A method according to claim 1 wherein the nerve electrode is a nerve cuff electrode.

3. A method according to claim 1 or 2 wherein the electrical signal is amplified, band-pass-filtered, and optionally rectified and bin-integrated when producing said further control signal.

4. A method according to claim 3 wherein the bin-integration is performed by means of an integrator having an adjustable integration period, said integrator being synchronized with the muscle stimulator.

5. A method according to any of claims 1-4 wherein the part of the body is innervated by the sensory nerve comprises a skin area.

6. An FES system for at least partially restoring the motor function of a human having at least one partially or completely paralyzed muscle, said system comprising:

a stimulator means for stimulating the paralyzed muscle or muscles

an implantable nerve electrode for sensing electrical signals from a sensory nerve which innervates a part of the body which is physiologically related to the partially or completely paralyzed muscle or muscles, and

control means responsive to the electrical signals sensed from said sensory nerve after the expiration of a predetermined period of time after the stimulation of the muscle for producing a further control signal for reactivating said stimulator means.

7. An FES system according to claim 6, wherein said control means comprises means for amplifying, band-pass-filtering, and optionally rectifying and bin-integrating the sensed electrical signal and means for producing said further control signal in response to said bin-integrated electrical signal.

8. An FES system according to claim 7, wherein the bin-integration is performed by means of an integrator having an adjustable integration period, said integrator being synchronized with the stimulator means.

9. A method for providing a secure grip of an object through FES of a partially or completely paralyzed muscle which is involved in holding the object, comprising

implanting a nerve electrode for sensing electrical signals from a sensory nerve which innervates a part of the body which is physiologically related to the partially or completely paralyzed muscle,

detecting the start of a slip of the object from the ENG signal from the nerve electrode,

and immediately upon detection of the start of a slip producing or modifying a control signal for activating a muscle stimulator and stimulating the paralyzed muscle in response to said control signal.

10. A method according to claim 9, wherein the start of the slip is caused by an external change in the load or weight of the object.

11. A method according to claim 9, wherein the start of the slip is caused by an internal disturbance such as fatigue.

12. A method according to claim 9, wherein the start of the slip i caused by a change in the frictional coefficient of the skin, such as due to sweating.

13. A method according to any of claims 9-12, wherein the start of the slip is detected automatically as an event that exceeds a predetermined threshold value.

14. A method according to claim 13, wherein the ENG recorded from the sensory nerve is processed using analog or digital circuitry, and a filtered version of the ENG is subtracted from the actual electrical signal sensed, thereby removing unrelated background activity from the signal, the resulting calculated signal being identified as a signal related to the start of a slip if it exceeds a predetermined value.

15. A method according to claim 14, wherein the filtered version of the ENG is delayed by a number of samples and then subtracted from the actual signal sensed.

16. A method according to claim 14 or 15, wherein the filtered version is a low-pass filtered version.

17. A method according to any of claims 9-16 wherein the actual signal is an unfiltered signal or a signal which has been subjected to filtering with a shorter time constant than the version subtracted.

ABSTRACT OF THE DISCLOSURE

The motor function of a partially or completely paralyzed muscle is restored by implanting a nerve electrode, e.g. a cuff electrode, for sensing electrical signals from a sensory nerve which innervates a part of the body which is physiologically related to the partially or completely paralyzed muscle, stimulating the paralyzed muscle by means of a muscle stimulator, sensing by means of said nerve electrode an electrical signal from the sensory nerve, producing a further control signal for reactivating the muscle stimulator dependent on the electrical signal sensed after the expiration of a predetermined period of time after the stimulation of the muscle, and restimulating the paralyzed muscle in response to said further control signal. The electrical signal is amplified, band-pass-filtered, and optionally rectified and bin-integrated when producing said further control signal. The bin-integration is performed by means of an integrator having an adjustable integration period, said integrator being synchronized with the muscle stimulator. A secure grip of an object through FES of a partially or completely paralyzed muscle which is involved in holding the object, is obtained by detecting the start of a slip of the object from the ENG signal from the nerve electrode and immediately upon detection of the start of a slip producing or modifying a control signal for activating a muscle stimulator stimulating the paralyzed muscle. The start of the slip is detected automatically as an event that exceeds a predetermined threshold value in that the ENG recorded from the sensory nerve is processed using analog or digital circuitry, and a low pass-filtered version of the ENG, delayed by a number of samples, is subtracted from the actual electrical signal sensed, thereby removing unrelated background activity from the signal.

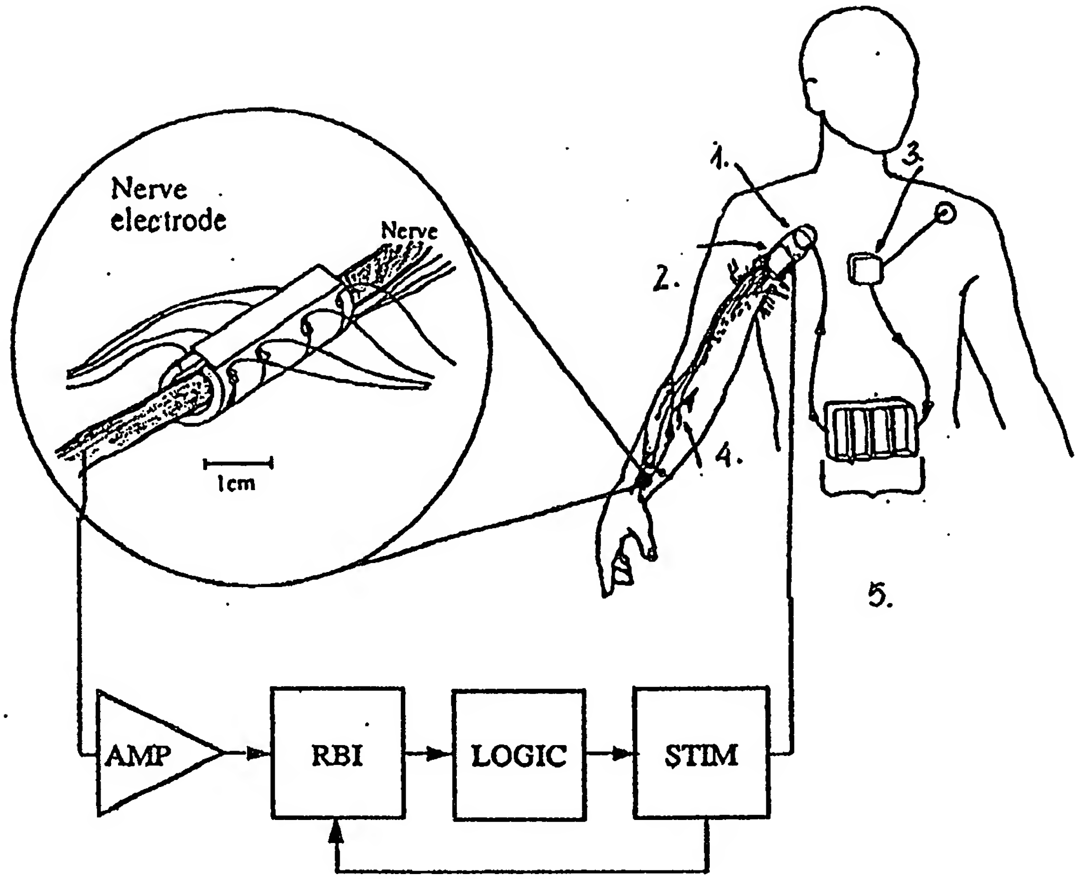



Fig. 1A

**Fig. 1 B**

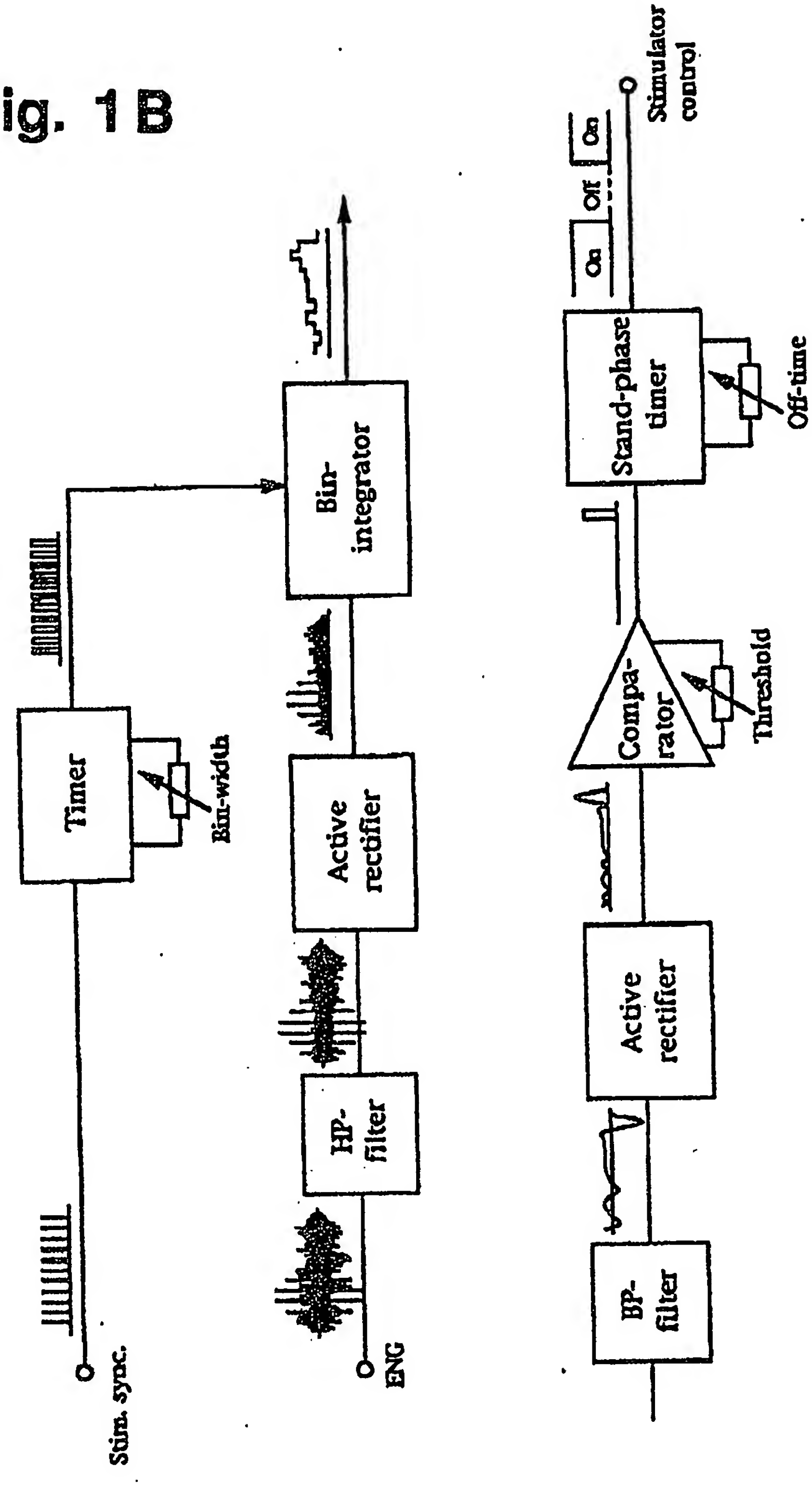
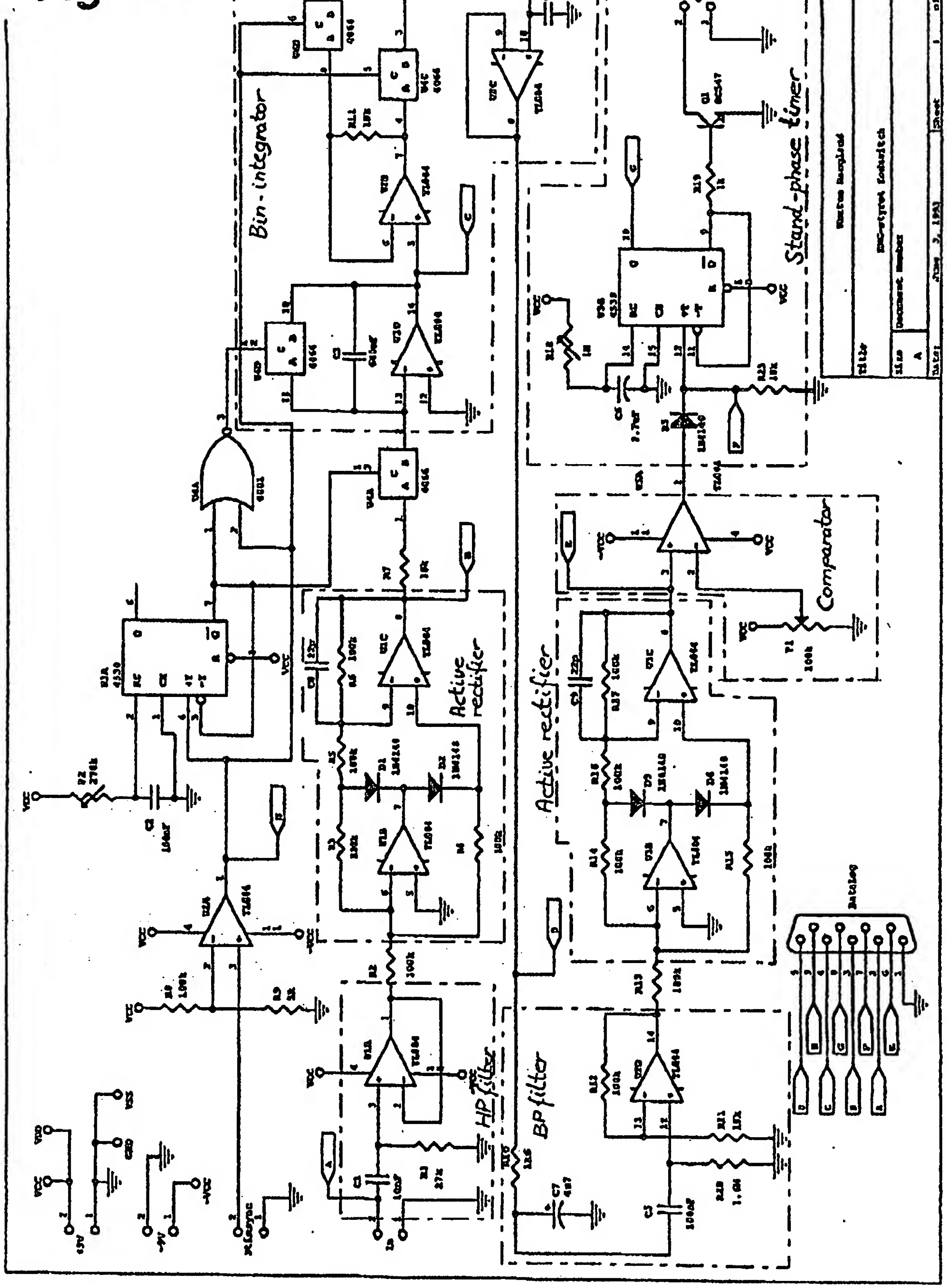
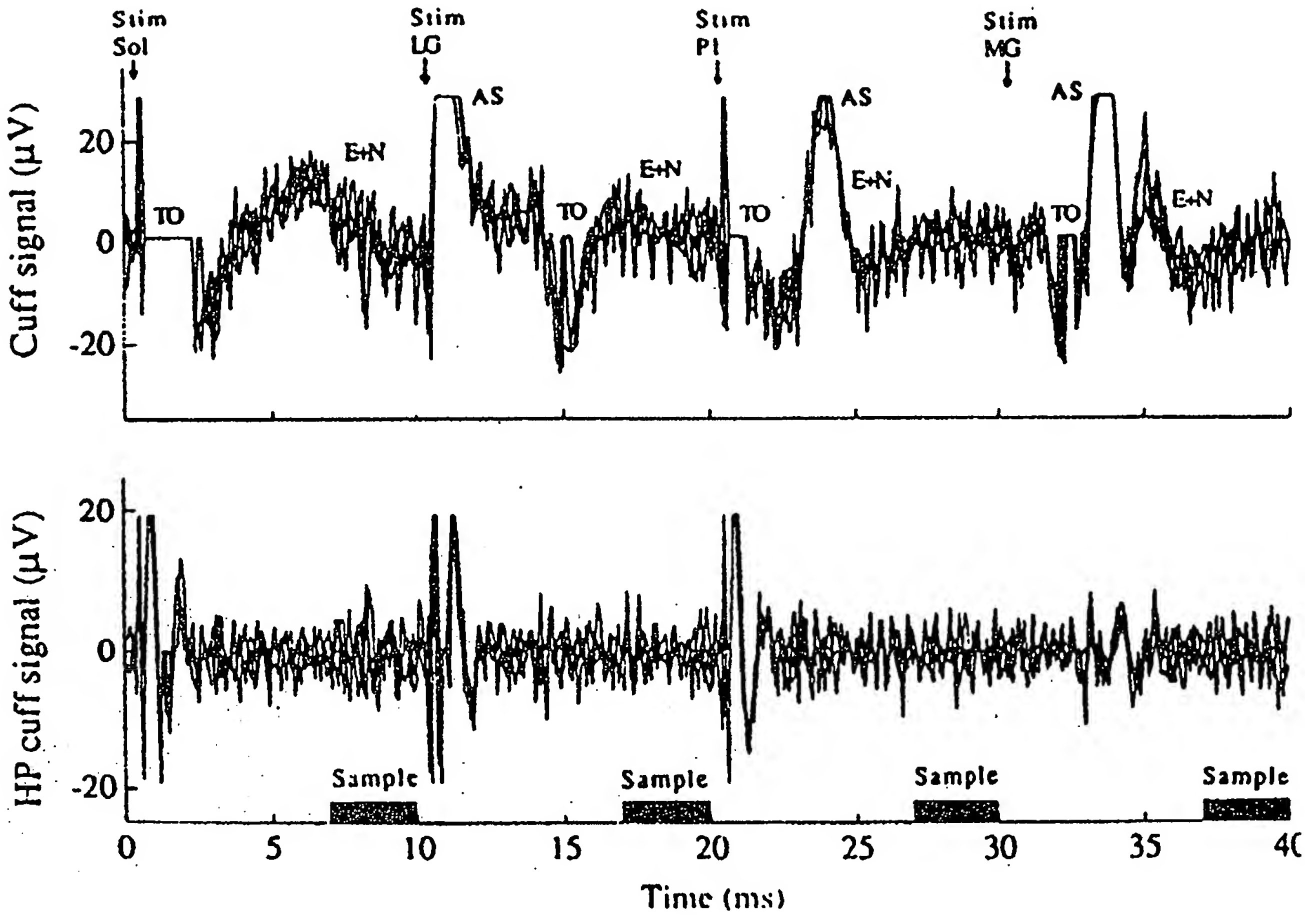

Stim. sync.
Timer
Bin-width
Bin-integrator
ENG
HP-filter
Active rectifier
BP-filter
Active rectifier
Compa-rator
Threshold
Stand-phase timer
Off-time
On
Off
On
Stimulator control

Fig. 10



Bin-integrator
Active rectifier
Comparator
Stand-phase timer
HP filter
BP filter

Fig. 2



Stim Sol
Stim LG
Stim PI
Stim MG
AS
E+N
TO
Cuff signal (μV)
20
0
-20
HP cuff signal (μV)
Sample
0
5
10
15
20
25
30
35
40
Time (ms)

Fig. 3

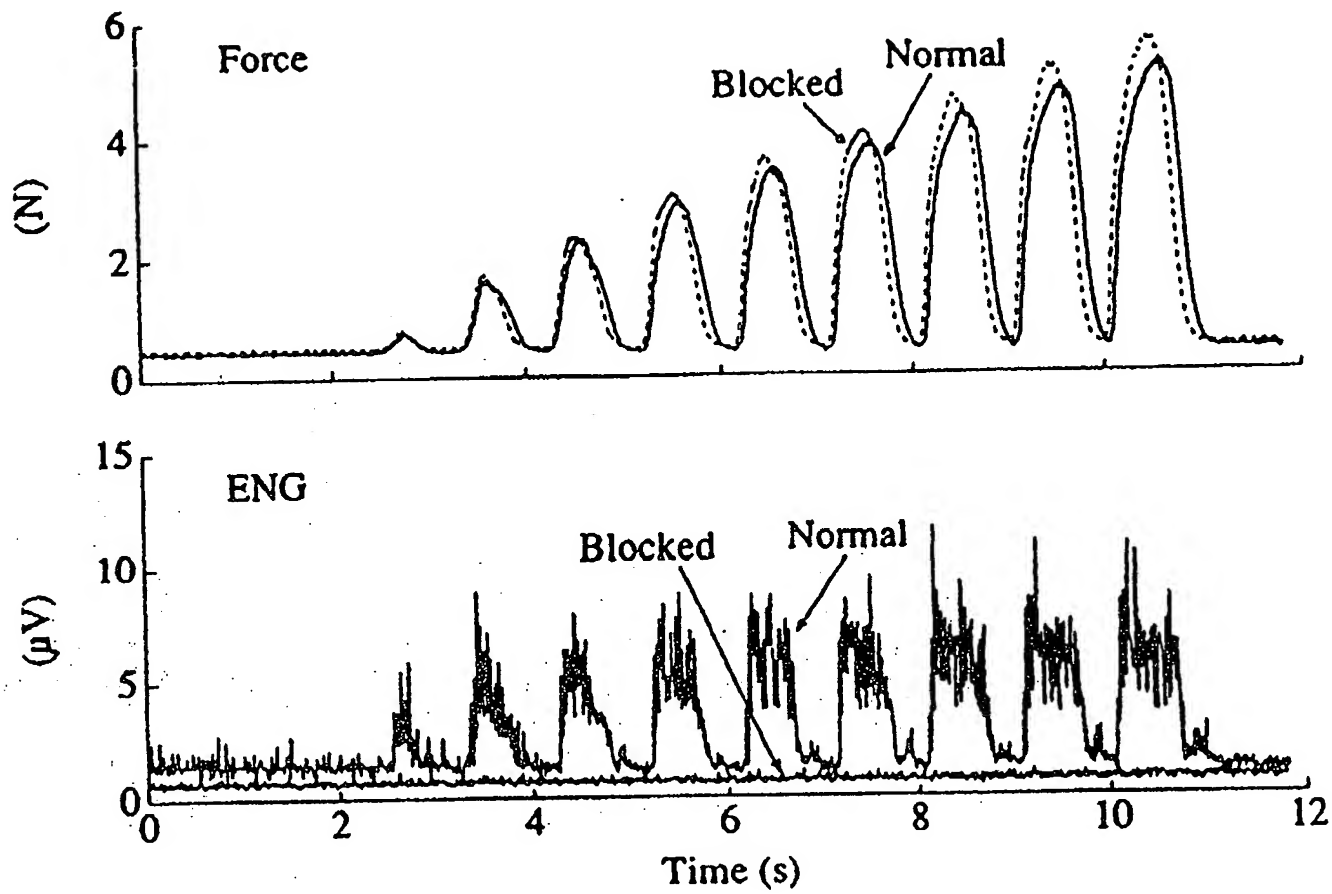
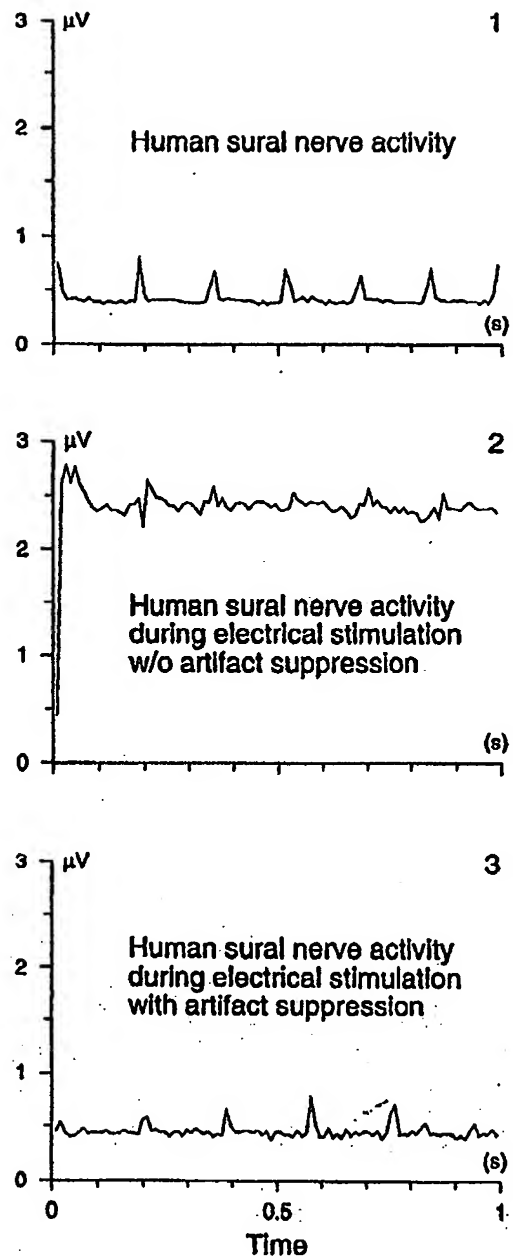

Force
Blocked
Normal
(N)
ENG
Blocked
Normal
(μV)
Time (s)
0
2
4
6
10
15
5
0
2
4
6
8
10
12

Fig. 4



µV
1
Human sural nerve activity
(s)
µV
2
Human sural nerve activity during electrical stimulation w/o artifact suppression
(s)
µV
3
Human sural nerve activity during electrical stimulation with artifact suppression
(s)
0
0.5
1
Time

2097857

Fig. 5